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SUPREME COURT, U. S

IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-501

WYETH LABORATORIES, a division of American Home Products Corporation, a Delaware Corporation,
Petitioner,

v.

EPIFANO REYES, individually and as next friend of Anita Reyes, a minor,
Respondent.

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF AMICUS CURIAE IN SUPPORT OF A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT.

THE CONFERENCE OF STATE AND TERRITORIAL EPIDEMIOLOGISTS

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The Conference of State and Territorial Epidemiologists, pursuant to Rule 42 of the Rules of this Court, hereby respectfully moves the Court for leave to file a brief *amicus curiae* in this case. Consent for the filing

of such a brief has been obtained from the petitioner Wyeth Laboratories, but has not been granted by attorneys for the respondent Epifanio Reyes.

Movant, the Conference of State and Territorial Epidemiologists, is a membership organization composed of the heads of the communicable disease programs of each of the fifty states, Puerto Rico, and the Virgin Islands. The Conference represents physicians and scientists who specialize in the field of epidemiology and who are engaged, along with other state officials and local health officers, in conducting public health programs for the control of diseases among the people. The Conference is an affiliate of the Association of State and Territorial Health Officers and is an official advisory group to the United States Public Health Service.

It is the intention of the epidemiologists of the country to call the attention of the Court to the dangerous effect which the decision below, if upheld, could have upon the nation's preventive medicine programs. A major keystone of these efforts is the extensive, community-wide use of immunological agents. In a quite literal sense, these products of scientific research have saved millions of lives and prevented untold misery among the people of the world.

We are sure that the members of this Court do not need to be reminded at length of the historical significance of immunization against disease. In past centuries, millions more people were killed by infectious and communicable diseases than by all the wars of man. Total populations were decimated in Europe

and Asia. These scourages have only recently come under control.

By its nature the Conference has a unique interest in the outcome of this litigation. Public health and epidemiology (the study of the distribution and determinants of diseases in man and the application of epidemiological methods to prevent disease) are fields of professional specialization. Programs of disease prevention are directed by governmental agencies of the Federal and State levels where epidemiologists play key investigative, analytical, and evaluative roles.

The decision to conduct a public health program to prevent a particular disease and to utilize a particular immunization agent is made by a trained epidemiologist on behalf of the public and after a very detailed, comprehensive review and balancing of risk and benefits. Any determination of the obligation of a manufacturer to disclose risks directly to participants in a public immunization program unavoidably affects the exercise of professional judgment by trained epidemiologists. The impact of the lower court's holding on the discharge of the epidemiologist's professional responsibility cannot be adequately raised and discussed by either the petitioner or the respondent.

In the opinion of the Conference, the decision below, if left standing by this Court, will seriously endanger disease prevention in the United States and have a highly deleterious effect on state and national efforts to control such epidemic diseases as poliomyelitis. The brief submitted by the Conference with this motion sets forth the particular issues which we believe merit the Court's consideration. We respectfully submit that

this case is one of importance to the nation's public health, and that review by the Court is merited.

Respectfully submitted,

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A. It is the Judgment of the Public Health Authorities of the States of the United States, the State Epidemiologists in Charge of Immunization Programs in the United States, that the Effect of the Decision of the Court Below Would Be To Endanger Very Seriously Disease Prevention in the United States.

This brief as *amicus curiae* is presented to the Supreme Court of the United States in support of the petition for a writ of certiorari in *Reyes* v. *Wyeth Laboratories,* 498 F.2d 1264 (5th Cir. 1974).

The Conference of State and Territorial Epidemiologists is a membership organization composed of the state-employed heads of the communicable disease programs of the state governments of the 50 states, Puerto Rico, and the Virgin Islands. The Conference represents physicians and scientists who specialize in the field of epidemiology, the study and control of epidemic diseases. The Conference is an affiliate of Association of State and Territorial Health Officers and is an official advisory group to the United States Public Health Service, working closely with the Center for Disease Control in Atlanta, Georgia.

It is the judgment of these state public health authorities that the effect of the decision of the United States Court of Appeals for the Fifth Circuit would be a very serious blow to state and national programs of disease control in the United States.

B. In Particular, the Effect of the Reyes Decision Would Be Felt in State and National Efforts to Control Poliomyelitis, a Very Serious Crippling and Killing Disease in the United States, at a Time When Immunization Levels are Already Becoming Dangerously Low in the High-Risk Populations of Children of Ages Up to Four Years.

The vaccine involved in the *Reyes* case was Sabin oral poliomyelitis vaccine, a biological product of very, very high safety and internationally proved effectiveness in immunizing humans against the disease of poliomyelitis. Because of the tragic results of this disease, especially among young children, the campaign to produce an immunizing agent was one of the priority areas of scientific research in this country and in other countries for many decades.

The development of the Sabin vaccine was one of the great triumphs of medical scientific research in this

century. The mass immunization programs of the late 1950s and the 1960s reduced very substantially the cases of poliomyelitis in the United States.

Now that these national mass immunization programs have been so very effective in reducing poliomyelitis in the adult population and among most children, the target group for national and state efforts is the children being born into the population without protection against the disease. The national government, through the U.S. Public Health Service and its Center for Disease Control, conducts two kinds of campaigns on a constant basis to obtain immunization of these high-risk children: (1) encouragement of public health clinics and privately practicing pediatricians and family physicians to immunize infants under their care as soon as possible in their lives; and (2) national support of vigorous campaigns of *mass immunization* of these high-risk children in any area of the country where poliomyelitis breaks out in epidemic proportions.

The child who contracted polio in this case, Anita Reyes, was at high risk for polio naturally in the community; in fact, she lived in the area of highest risk in the United States at that time, Hidalgo County in Texas, close to the Mexican border. The second-mentioned type of national campaign against a local epidemic was in force at the time in southern Texas under the guidance and surveillance of the state epidemiological authorities and the U.S. Public Health Service. The efforts of the State and the U.S. Public Health Service and the scope of the epidemic are described in the official publication of the Center for Disease Control, *the Morbidity and Mortality Weekly Report,* for May 30, 1970. The Federal policy of mass immuni-

zation with Sabin vaccine for the control of local outbreaks of the disease is described graphically in a series of such campaigns in the above publication over a period of years leading up to and including the particular epidemic in which the Reyes child contracted the disease. These reports are cited in Note 1 at pages 16 and 17 of the petition of Wyeth Laboratories for the writ of certiorari. This series of reports, more than anything else we could cite, proves the national significance of these immunization programs and proves their *success in controlling the spread of the disease* through this use of Sabin vaccine on a mass basis in clinics and doctor's offices.

The result of enforcement of the decision below could seriously jeopardize *both* the general campaign to immunize young children, and the vigorous national campaigns to control epidemics among such small children, as in southern Texas.

C. The Effect of this Decision Would Be To Require a "Warning" to Parents of Young Children Who Are at High Risk for Poliomyelitis in the Community Against the Extremely Small, Almost Unmeasurable Risk at the Present Time (From 1 in 2 Million to 1 in 15 Million Doses) from the Vaccine Itself. The Requirement of Such a Warning To Be Given by the Commercial Drug Company Marketing the Product Would Violate the Accepted Practices of State and National Epidemiologists.

D. In the Reyes Case Situation, Such a Warning by the Drug Company Could Create Alarm in the Public in the Face of a Natural Epidemic. The People Are Already Resisting Taking the Vaccine Because They Think Polio Is "Conquered." The Rates of Immunization in Children are Constantly Going Down. These Children Aren't "Sick" and the Parents Have Little Incentive To Take Them for Immunizations, Particularly If They Have No Regular Family Pediatrician or Doctor. The "Warning" Would Not Only Further Discourage Such Parents, but, in Epidemic Situ-

ations, Would Lead the Community To Assume that the Infected Children Around Them Might Have Gotten the Disease from the Vaccine and So Would Further Reduce Immunization, Even with Assurances from Officials that the Epidemic Was from Natural Causes.

It should be realized that Sabin poliomyelitis vaccine is an extremely safe product, much safer than the vast majority of all types of products for human consumption. In large part, this is due to the high level of safety required by the Federal Government for the marketing of all biological products. Also, we are able to provide statistics on the safety of Sabin vaccine to a much greater degree of certainty than on most products because of the unprecedented international testing of the vaccine in all parts of the world and the close surveillance of the outbreak of communicable disease in this country by the national and state governments. The opinion of the Court in the Fifth Circuit in *Reyes* does not contradict this conclusion. The Court specifically found that the vaccine was not unreasonably dangerous. This is a vast understatement. The Court nevertheless found the product "defective," its conclusion of liability under a products liability theory, on the sole basis that a direct warning to the purchaser or user (the child and her parents) was not given by the manufacturer.

The Sabin vaccine is a prescription drug. A detailed package insert accompanied the drug and provided to physicians, public health authorities, and clinic personnel a detailed description of the vaccine, its use, and its contraindications. Plaintiff in this case in no way challenged the content of the warning in the package insert. The description therein had the specific approval of the Federal Division of Biologics Standards. It should be noted that the package insert

itself proves the very high degree of safety of the vaccine in use here. The package insert pointed out that the vaccine had no known side effects. In general use, there were no recommended precautions or contraindications to its use. Few products of any kind, even after marketing, are free of defects in this high degree. The only specific precautions made in the insert do not relate to the safety of the product, but to its effectiveness in being retained by the patient, or its effectiveness in a patient who may already have polio. The insert suggests that the vaccine not be given to individuals suffering from "acute illness, other than minor, afribrile upper respiratory infection" and "in the presence of persistent vomiting or diarrhea."

As to the inherent risk in the vaccine of producing polio, the statistics concerning the risk as set forth in the package insert in children under 5 years of age are as follows: from Type III, 0.53 per million doses; from Type I 0.17 per million; and for Type II, none. The alleged contracting of polio in the plaintiff was from Type II. In the *Reyes* case, therefore, the "warning" would have been of a statistical risk of about 1 in 5.88 million! It should be clear that this is *not* a risk of proved vaccine-produced disease. It is merely statistically possible cases within the period of biological compatability.

Under these conditions, it was not the practice of epidemiologists or physicians to give a "warning" to parents or to children of this statistically remote possibility of contracting polio from the vaccine. Such a low risk would be very remote in relation to benefit in any medical, therapeutic situation. In preventive medicine, where the child or other recipient is not "sick," it is even more difficult for the patient to weigh

risk and benefit. At present, the immunization rate in children is going down steadily because so many parents think that the disease of poliomyelitis is "conquered" and there is no sense in taking the trouble or expense of immunization. In early October of 1974, the Center for Disease Control released figures indicating that immunization levels for children of 1-4 had dropped in 1973 to 60.4 percent. (*New York Times*, Oct. 10, 1974, at p. 10.) On a nationwide basis, this means that 40% of these children are not immunized; a level at which the disease could certainly burst out in epidemic proportions among this huge population of children at risk.

In the face of this problem the *Reyes* decision would require this alarming warning to be given by the manufacturer to the parents. The alarming nature of the warning does not relate so much to the statistics of the risk, which many people would not fully understand anyway. It would relate to the risk of "polio," a dreaded disease in children, which could be fatal or result in severe crippling. Yet, the *benefit* of the vaccine would be to prevent this very same dread disease and risk of death and crippling. In the *Reyes* situation, the risk of natural polio in the community was vastly greater than from the vaccine. The evidence at the trial was not contradicted that there was an epidemic at that time that in Hidalgo County and Dr. Neal Nathanson, Professor of Epidemiology at Johns Hopkins University School of Public Health, placed the risk to the Reyes child at 1 in 3000 children in her age group. (Record, p. 1381)

Under these conditions, the practice was clear. A warning of this kind was not given by the epidemiologists or in the public health clinic where Anita Reyes received the vaccine. To do so would, in the view of

the professionals involved, have unduly alarmed parents and discouraged them from bringing the children for immunization. If the drug company were to be required to provide a warning in some broadcast nature, or by signs in the clinic, or by written notices, the parents could further be suspicious of the public health authorities for encouraging immunizations, and could suspect that the outbreak of cases of polio was caused by the vaccine rather than by the natural epidemic. This fear would be very difficult to combat. The fact that the early cases had occurred before a mass program of immunization had begun would be obscured or not noticed. Statistically compatible cases would be publicly attributed to the vaccine and all efforts to combat the disease would be compromised.

E. The Fifth Circuit Opinion Requires a Direct Warning by the Manufacturer to the Public in Contravention of Texas Law and the Federal Food, Drug, and Cosmetic Act of 1938 Regarding Prescription Drugs.

The opinion of the Court of Appeals is contrary to Texas law and Federal law in requiring a direct warning to the public on risk concerning a prescription drug. The Court did not challenge the fact that the vaccine was licensed by Wyeth as a prescription drug. It would have been a violation of law for the manufacturer to advertise to the public or to provide a warning to patients in the public health clinic where Anita Reyes received her vaccine. The same conditions existed at the clinic as in a private doctor's office in that this was regular medical care. It was not a mass distribution of the vaccine in a school or gymnasium as occurred in the late 1950s and 1960s, or as in the *Davis* case cited below. *Davis* v. *Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968).

We firmly disagree with the opinion below that the method of delivering medical care in this public health clinic was *not* such that the vaccine was administered as a prescription drug. The clinic was operated and supervised by physicians. A trained clinical, public health nurse, in accordance with accepted medical practice, gave the vaccine as she would a "shot" with a hypodermic needle, or as she would offer other clinical services.

There is nothing in the law of Texas or the Federal food and drug laws which supports removing the restrictions on prescriptive drugs because they are administered in a public health clinic. In fact, the leading case on the prescriptive drug manufacturer's duty in Texas, *Gravis* v. *Parke-Davis and Co.*, 502 S.W.2d 863 (Tex. Civ. App.—Corpus Christi., 1973) includes not only physicians, but "other authorized persons" in the group who administer the drugs under prescription. This group of "authorized persons" would certainly include clinical nurses administering drugs of this type in a clinic. The *Gravis* case specifically holds "These professionals are in the best position to evaluate the warnings put out by the drug industry." 502 W.W. 2d at 870. The public health nurses, as well as the physicians, in the *Reyes* situation received the full warning from the manufacturer, Wyeth Laboratories. That warning was evaluated and the physicians and nurses made the professional judgment not to pass on this extremely small risk information to the parents. There is nothing in the Texas law to support any other position. The Court of Appeals attempts to avoid this Texas law by an unsupported assertion that the drug was not distributed as a prescription drug. This distinction has no support in Texas law and conflicts with the *Gravis* case

in including "other authorized personnel" in administering prescription drugs.

The decision of the Fifth Circuit in *Reyes* also is in conflict with the decision of another panel of the same Circuit in interpreting Texas law on warnings to patients by physicians. *Karp* v. *Cooley.*, 493 F.2d 408 (5th Cir. 1974). In that case, the Court upheld the settled Texas law that the scope of the warning in an informed consent of the patient is governed by medical practice and the judgment of reasonable medical practitioners in the same or similar circumstances. Expert testimony was required to provide proof of the accepted medical standard. Had this rule of Texas law been applied in *Reyes*, the plaintiff would have failed to meet this requirement of proof. It was unrebutted that the accepted practice of public health programs, physicians, and nurses was not to warn of the remote risks to the Reyes child in receiving the vaccine in the light of the vastly greater benefits to be derived in receiving it during an epidemic outburst of polio in Texas. It was error under Texas law to allow a jury to contradict this judgment of medical professionals and to require a warning by the manufacturer. See also *Wilson* v. *Scott*, 412 S.W.2d 299 (Tex. 1967).

F. The Circuit Court Committed Error in Not Reversing the Trial Court's Denial of the Defendant's Motion for a Directed Verdict and Judgment in View of the Overwhelming Medical and Scientific Proof that the Reyes Child's Disease Was Not Caused by the Vaccine.

The Conference of State and Territorial Epidemiologists must also support the petition for a writ of certiorari on the grounds that the Court of Appeals committed reversible error in not reversing the trial court's denial of a directed verdict and judgment,

n.o.v., on the basis that the medical and scientific evidence was overwhelmingly in favor of the defense that the Reyes child did not contract her disease from the vaccine but as a result of the natural epidemic in the community.

The Conference is a group of scientists. It is interested in the administration of justice as bearing some direct relationship to scientific truth and findings. When decisions fly in the face of overwhelming scientific proof to the contrary, particularly in the field of immunology and epidemiology wherein the Conference of State and Territorial Epidemiologists has its own expertise and experience, this can be described only as very disturbing.

The defense in this case produced an unrebutted picture of a united medical and scientific community that there was no proved causal relationship between the Reyes child's disease and the vaccine. The head of the Federal Government's agency regulating this field, himself a respected scientist, testified for the defense as did the head of the Federal Government's laboratory in the field. Outstanding experts in virology, epidemiology, and pediatrics from the nation's leading universities testified. In rebuttal, the plaintiff produced as an "expert" only the local general practitioner who treated the Reyes child *after* she had contracted the disease.

In the face of this overwhelming evidence, the Court of Appeals asserted that this was "conflicting credible evidence" and "within the jury's prerogative." The Court, in an incredible understatement, said that "The evidence for Wyeth was *somewhat* persuasive; there is no doubt about it." (Emphasis supplied.) The Court then asserted that the evidence for Reyes "was

substantial and at least as persuasive, looking at the record coldly." 498 F.2d at 1289.

It seems to this *amicus* that no review of this record can support this last statement. To arrive at it, the Court and jury would have to reject all of the expert testimony *plus* the overwhelmingly high statistical probability that the Reyes child's disease was natural. The risk *at most* in the vaccine was 1 in 5.88 million. In natural disease in the community it was 1 in 3000. Only the patient's own doctor, a general practitioner, gave his opinion that the vaccine *caused* the disease.

The Texas law requires that questions of medical and scientific causation be determined on the basis of expert testimony. Such determinations must be based on reasonable probability. The burden of proof here was on the plaintiff, not on the defendant. All of the weight of the expert evidence and scientific probability was overwhelmingly on the side of the defense. Under the instructions given by the trial judge, the jury was allowed to dismiss all of the National Government officials and all of the scientific experts as long as they "believe" Dr. Casso. The jury was obviously troubled by the charge, since they came back and asked what "preponderance" of the evidence meant. The *only* explanation the trial judge gave them was that preponderance did not depend on number of witnesses. The only meaning the jury could give to this was that, if they found Dr. Casso credible, they could ignore the array of experts. They could ignore both numbers and quality of testimony in a *scientific* judgment. The trial judge gave as an example that they could believe one expert who said a horse was white as against ten who said it was black.

This interpretation of a jury's prerogatives is in direct contradiction of two other leading decisions of

this same Fifth Circuit Court of Appeals. In *United States* v. *Hoxsey Cancer Clinic*, 198 F.2d 273 (5th Cir. 1952) the Court rejected as entitled to no weight the opinions of general practioner osteopaths on the cause of cancer and reversed a jury determination. In *United States* v. *Weir*, 281 F.2d 850 (5th Cir. 1960) the Court rejected the testimony of five general pracitioners as *not substantial evidence* in the field of arthritis in opposition to an array of experts in the field. We submit that these cases represent an enlightened and proper application of the law to cases requiring expert, scientific evidence. In *Reyes*, we have an example of an erroneous application of a discredited practice of not upsetting jury verdicts if there is any evidence to support them. In a simple case of credibility, this rule may make sense on an appellate level. It does not make sense or justice in a complex, scientific case where expert, scientific evaluation is essential to any proper conclusion and where the statistical probabilities are overwhelmingly against the party bearing the burden of proof. Neither the evidence nor the statistical probabilities supported the plaintiff herein. We therefore support the petition for a writ of certiorari.

Respectfully submitted,

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